

EXPANDABLE STENT WITH ARRAY OF RELIEF CUTS

Cross Reference to Related Applications

This is a continuation-in-part of U.S. patent application Serial No. 09/357,699 filed July 20, 1999 and entitled EXPANDABLE STENT and is a Continuation of U.S. patent application Serial No. 09/774,760 filed January 30, 2001.

Background and Brief Summary of the Invention

The present invention relates generally to balloon expandable and self-expanding stents. More particularly, the present invention provides an array of relief cuts for use in a variety of stent designs. According to the present invention, the relief cuts are strategically placed to allow the stent to expand more easily, requiring less pressure for the expansion, without any significant loss of columnar compressive strength of the members making up the stent. The present invention allows the use of wider and thinner material, resulting in a stent with greater radio-opacity, and resulting in a thinner walled stent allowing maximum blood flow through the artery or other lumen.

The prior art stent designs typically use stent members or struts having circular cross sections as illustrated in Figs. 4B, 4C and 4F or generally square cross sections as illustrated in Fig. 4H. Fig. 4A illustrates a typical prior art diamond-shaped cell configuration utilizing the cross sections illustrated in Figs. 4B, 4C, 4F and 4H. The prior art configurations illustrated in Figs. 4A-4C and 4H have several disadvantages. First, as the stents are downsized for use in smaller vessels, the circular or cross sections of the stent material tends to effectively reduce the cross-sectional area of the artery or other body lumen which is capable of achieving low turbulence or laminar blood flow. A second disadvantage of this typical prior art design is that, in many instances, particularly as the stent size is reduced, the radio-opacity of the stent, i.e., the capability of the stent to be viewed by the surgeon, is reduced. A third disadvantage is limited coverage of the vessel wall by the stent. The present invention is designed to overcome these problems by providing a wider and thinner material, as illustrated

1 generally in Figs. 4D, 4E and 4G, which provides enhanced radio-opacity, enhanced vessel
2 wall coverage but at the same time providing a stent that will expand as easily as the prior art
3 stent. For example, the stent, according to the present invention, as illustrated in Figs. 4D,
4 4E and 4G, is designed to expand under the same balloon pressure as the stent designs
5 illustrated in Figs. 4A-4C and 4H.

6 The prior art also includes International Application No. PCT/US99/06136 published
7 October 7, 1999 as publication No. WO 99/49810. That published application discloses a
8 "double-strut" stent configuration with a plurality of closed cells wherein each member of the
9 cell configuration is slotted throughout its entire length. The inherent weakness of this design
10 is that each fully slotted cell member becomes significantly weakened by the use of slots
11 extending throughout its entire length. The compressive strength of each member is
12 substantially weakened as shown by the "critical load" analysis as an "Euler column" as
13 established mathematically by Leonard Euler. The removal of approximately one-third of the
14 material along the center of a column and throughout the entire length of the column greatly
15 reduces its ability to support a compressive load, i.e., its hoop strength in the case of a stent.

16 In contrast to the "double-strut" design described in the above-identified PCT
17 International application, the present invention utilizes an array of strategically placed relief
18 cuts. Each individual relief cut has a relatively short length in order to preserve the ability of
19 the member to retain its columnar compressive strength.

20 It is also known in the prior art to electro-polish portions of a stent to reduce the cross-
21 sectional area of a stent member so that less balloon pressure is required to expand the stent.
22 The electro-polishing technique is expensive and has the inherent weakness of reducing the
23 radio-opacity of the polished portion of the stent. It is important to maximize the radio-opacity
24 of the stent, especially as smaller stents are used in smaller arteries and other body lumens.
25 The present invention avoids the cost and disadvantages of electro-polishing; furthermore,
26 the present invention inherently allows the use of wider and thinner, more radio-opaque stent

1 members.

2 Another significant problem with most prior art stent designs arises when a stent is
3 placed in a curved section of an artery (or other lumen). As the balloon is expanded, the stent
4 tends to straighten, causing the curved portion of the artery (or other lumen) to straighten and
5 sometimes rupturing the vessel wall. The present invention facilitates expansion of a stent
6 in a curved artery by using curved balloons and applying relief cuts in selected, predetermined
7 patterns to the stent. The relief cuts reduce the tendency of the stent to straighten as the
8 stent and balloon are expanded.

9 A further limitation of prior art stents is that the typical stent expands at a uniform rate
10 as balloon pressure is applied. There are many practical instances where a controlled non-
11 uniform expansion of a stent would be a significant advantage.

12 Another significant aspect of the present invention is that selective placement of an
13 array of relief cuts on a stent allows the stent to expand in a predetermined and controlled
14 non-uniform fashion. For example, placing an array of relief cuts only in the longitudinal
15 center region of the stent causes the center region of the stent to expand first before the distal
16 and proximal regions of the stent expand. As another example, relief cuts can be utilized only
17 at the distal and proximal end regions of the stent, which causes the end regions to expand
18 first, with the central region of the stent expanding last. As a further example, relief cuts may
19 be applied in various patterns to cause stents to act differently; some patterns allow stents to
20 be used better in curved and tapered vessels, some patterns allow one or both ends of the
21 stent to be "flared," and some patterns allow the stent to bend more easily in a given direction.

22 Another advantage of the present invention is that the relief cuts may be applied to a
23 variety of existing and commercially successful balloon expandable and self-expanding stent
24 designs. The use of the relief cuts as described and claimed herein can quickly provide
25 existing commercial stents with most, if not all, of the advantages of the present invention.

26

1 It is therefore a primary object of the present invention to provide an array of relief cuts
2 in a balloon expandable stent to allow the stent to expand more easily and with less pressure,
3 without any significant loss of the columnar compressive strength of the stent members in
4 which the cuts are formed.

5 Another object of the invention is to provide an array of relief cuts in prior art stent
6 designs to allow those stents to expand more easily and with less pressure than is the case
7 in the absence of relief cuts.

8 Still another object of the invention is to provide a balloon expandable and self-
9 expandable stent design having an array of relief cuts which in turn allows the use of wider
10 and thinner members in the stent to increase the radio-opacity and vessel wall coverage of
11 the stent, while using thinner wall members.

12 Still a further object of the invention is to provide an array of relief cuts which not only
13 allows the use of wider members, but also allows the use of thinner wall stents, thereby
14 increasing the effective inner diameter of arteries and other lumens carrying those stents. The
15 use of thinner walled stents minimizes the profile or cross section of the stent and provides
16 more clearance in inserting and deploying the stent.

17 A still further object of the invention is to provide selective placement of one or more
18 arrays of relief cuts to a stent, which allows the stent to expand in a predetermined and
19 controlled non-uniform fashion. This feature allows a stent to be custom designed to an artery
20 to better support the arterial wall and to seal end leaks.

21 Other objects and advantages of the present invention will become apparent from the
22 following description and the drawings wherein:

23 Brief Description of the Drawings

24 Figs. 1A-E are schematic representations showing relief cuts according to the present
25 invention as applied to a generally diamond-shaped prior art stent cell configuration;
26

1 Fig. 2 is a schematic representation illustrating how the relief cuts of the present
2 invention may be applied to a prior art "butterfly" stent cell configuration;

3 Fig. 3 is a schematic representation showing how the relief cuts of the present
4 invention may be applied to a prior art stent configuration having an undulating or sinusoidal
5 -type cell configuration;

6 Figs. 4A-4C and 4F illustrate a prior art, diamond-shaped stent cell, with Figs. 4B and
7 4C showing the cross section of the stent of Fig. 4A;

8 Figs. 4D, 4E and 4G illustrate how the present invention as applied to the diamond-
9 shaped cell of Figs. 4A-4C and 4E achieves a wider, thinner stent, with a larger interior
10 diameter allowing less turbulent blood flow;

11 Fig. 4H illustrates the cross section of a typical prior art stent having a generally square
12 shape with rounded corners formed by electro-polishing;

13 Figs. 5A-5D illustrate how the relief cuts of the present invention may be applied
14 strategically to the distal and proximal ends of a stent, thereby causing those ends of the stent
15 to expand before the central portion of the stent expands;

16 Figs. 6A-6C are schematic representations illustrating how a pattern of relief cuts
17 placed only in the central portion of a stent will cause that center portion of the stent to expand
18 before the end portions;

19 Fig. 7 is a schematic representation showing how the relief cuts of the present
20 invention as applied to only the central portion of a prior art stent configuration will cause a
21 predetermined, controlled, uneven expansion of the stent;

22 Figs. 8A and 8B are schematic illustrations representing how the present invention
23 could be utilized to seal off the blood flow to and kill a cancerous tumor;

24 Fig. 9 is a schematic representation showing how relief cuts of the present invention
25 may be used in a prior art stent having a single strand serpentine-shaped stent, illustrating
26 how the present invention is usable in prior art stents which do not have closed cell

1 configurations;

2 Fig. 10 is a schematic representation of an alternate embodiment of the invention,
3 showing transversely spaced relief cuts for use primarily on stents having relatively wide
4 members;

5 Fig. 11A illustrates schematically how relief cuts may be patterned for use on a stent
6 to be placed in a curved artery or other body lumen wherein no relief cuts are placed in the
7 central region of the stent;

8 Fig. 11B is a section on the line 11B-11B of Fig. 11A;

9 Fig. 12A is a schematic representation showing still another way in which relief cuts
10 may be patterned on a stent for use in a curved artery or other body lumen;

11 Fig. 12B is a sectional view on the line 12B-12B of Fig. 12A;

12 Fig. 13A shows another embodiment wherein relief cuts are placed only in the central
13 region of a stent and around the entire periphery of the stent for use in a curved artery and

14 Fig. 13B is a sectional view on the line 13B-13B of Fig. 13A;

15 Fig. 14A is yet another embodiment showing relief cuts applied only to the central
16 region of the stent for use in a curved artery wherein the relief cuts are placed away from the
17 inside radius of curvature of the artery;

18 Fig. 14B is a section on the line 14B-14B of Fig. 14A;

19 Figs. 15A and 15B are schematic illustrations showing how the present invention may
20 be used with bifurcated stents;

21 Figs. 16A and 16B are schematic illustrations showing how the present invention may
22 be used in an irregularly shaped artery (or other lumen);

23 Figs. 17A and 17B are schematic illustrations showing one way in which the present
24 invention may be utilized in an artery (or other lumen) having a branch artery (or lumen) at or
25 near the deployment site of the stent;

26

1 Figs. 18A and 18B are schematic illustrations showing a second way in which the
2 present invention may be utilized in an artery (or other lumen) having a branch artery (or
3 lumen) at or near the deployment site of the stent; and

4 Figs. 19A and 19B illustrate how the present invention may be utilized in a stent having
5 cells which expand in different directions as the stent expands.

6 Detailed Description of the Drawings

7 Figs. 1A-1E illustrate how a conventional, diamond-shaped stent cell 10 may be
8 provided with relief cuts of various shapes according to the present invention. Fig. 1A
9 illustrates a diamond-shaped cell 10 having upper members 11 and 12 connected at their
10 intersection 13 and lower members 14 and 15 connected at their intersection 16. As the stent
11 cell 10 expands, members 12 and 15 flex or bend relative to each other at their connection
12 point 18. Similarly, members 11 and 14 bend or flex relative to each other about their
13 connection point or apex 19. Connection points 18 and 19 extend along the longitudinal axis
14 of the stent.

15 According to the present invention, a plurality of relief cuts shown generally as 30
16 includes first and second cuts 31 and 32, each formed either in the apexes or connections
17 between members or at the point in which the primary amount of flexing or bending occurs to
18 allow the stent to expand. The relief cuts of the present invention may also be utilized in
19 stents which do not use a closed cell configuration, as described below. The relief cuts 31
20 and 32 illustrated in Fig. 1A are arcuate cuts that extend completely through the particular
21 members of stent 10. Placement of one or more of the relief cuts 31 and 32 at or near at least
22 one designed flexion or bending point of the particular stent configuration allows the stent to
23 expand in response to considerably less balloon pressure.

24 Fig. 1B illustrates the same stent cell configuration as Fig. 1A but illustrates a second
25 form of relief cuts 35 which include a plurality of circular cuts 36 and 37, preferably positioned
26 at those points of the stent design which are intended to flex or bend to allow the stent to

1 expand. Fig. 1C illustrates a third embodiment wherein the relief cuts 40 are elliptical relief
2 cuts 41 and 42.

3 Fig. 1D illustrates a fourth type of relief cut 45 which includes a plurality of triangular
4 shaped cuts 46 and a second plurality of triangular cuts 47. Applicant believes that, although
5 the triangular relief cuts would perform the intended function of allowing the stent to expand
6 with less balloon pressure, those are not the preferred designs. The applicant believes the
7 designs having sharp corners in the relief cuts may eventually cause cracking of the stent
8 material as the stent expands.

9 Fig. 1E illustrates a fifth form of relief cut 50 including a first plurality 51 and a second
10 plurality 52 of generally rectangular or square shaped cuts. Again, these are less preferable
11 than the rounded cuts illustrated in Figs. 1A-C but, nevertheless, are within the scope of the
12 invention.

13 Fig. 2 illustrates a second stent cell configuration 110 having a "butterfly" shape
14 including a first butterfly wing 111 and a second butterfly wing 112. A plurality of arcuate relief
15 cuts 131-138 are formed strategically at those places of the cell configuration wherein
16 maximum bending and flexing is intended to occur between the individual members of the cell
17 configuration 110 as the stent expands. Fig. 2 illustrates the arcuate slotted relief cut.
18 Alternately, the circular or elliptical relief cuts illustrated in Figs. 1B and 1C could be utilized
19 in the cell configuration shown in Fig. 2.

20 Fig. 3 illustrates the application of the present invention to a third type of prior art cell
21 configuration 150. Cell 150 is generally a sinusoidal wall cell configuration. Relief cuts 151
22 are formed between adjacent members 152 and 153. Members 152 and 153 are intended to
23 flex or bend at their connection point 154 as the stent cell 150 expands. Relief cuts 151,
24 according to the present invention, are a series of round holes placed at this region of
25 maximum flexion or bending to allow the stent to expand in response to reduced balloon
26 pressure.

1 Figs. 4A-4H are intended to illustrate how the present invention can be applied to a
2 prior art cell configuration, and these figures illustrate some of the significant advantages that
3 the present invention provides. Figs. 4A-4C and 4H illustrate the prior art diamond-shaped
4 cell configuration 10 illustrated in Fig. 1. As shown in Fig. 4A, the cell configuration is shown
5 as it is used in the prior art, i.e., without any of the relief cuts of the present invention. Figs.
6 4B and 4C show one typical cross section of members 12 and 15 as being of circular cross
7 section and having a thickness t_1 and width w_1 that are equal to each other. Fig. 4H illustrates
8 a second typical prior art cross section as generally square with rounded corners formed by
9 electro-polishing, having a thickness t_1 and width w_1 . Fig. 4F shows in exaggerated fashion
10 a cross section of an artery 9 in which a stent having the cell configuration shown in Fig. 4A
11 has been placed. Member 12 is illustrated having a circular cross section and supporting
12 vessel wall 9. As shown in Fig. 4F, the central unobstructed portion of artery 9 has a diameter
13 d_1 which is the diameter of the stented artery capable of supporting low turbulence or laminar
14 blood flow, for a given degree of expansion of artery 9

15 Figs. 4D, 4E and 4G illustrate a modified diamond-shaped cell configuration 10a
16 incorporating the present invention. A series of circular relief cuts 37 are shown at the
17 intersection 18a of cell members 12a and 15a and illustrated best in Fig. 4E and are much
18 wider and much thinner than the prior art cross sections shown in Figs. 4B, 4C and 4H. The
19 width w_2 is considerably greater than the width w_1 of members 12 and 15; width w_2 is also
20 greater than the thickness t_2 of the modified cell configuration 10a. Width w_2 is preferably
21 between 1.5 and 5 times as great as thickness t_2 . However, it is significant to note that,
22 because of the presence of relief cuts 37, the modified cell configuration 10a will expand in
23 response to the same balloon pressure or less balloon pressure required to expand the prior
24 art cell configuration 10. The presence of relief cuts 37 in the cell configuration allows the use
25 of much wider and thinner members 12a and 15a of the stent. A further significant advantage
26 is illustrated in Fig. 4G. Each stent member 12a has the general configuration illustrated in

1 Fig. 4E and is shown in place within the same arterial wall 9 expanded to the same extent as
2 illustrated in Fig. 4F. The reduced thickness of each stent member 12a allows a larger
3 diameter d_2 which represents the unobstructed inner diameter of the stented artery capable
4 of supporting less turbulent blood flow. Any increase in this diameter is very significant,
5 particularly as smaller diameter or diseased vessels are considered. The effective volume of
6 less turbulent laminar blood flow varies with the square of the diameter d_2 so that the
7 difference illustrated between Figs. 4F and 4G represents an approximately 50% increase in
8 theoretical volumetric low turbulence, laminar blood flow in the stented artery for the same
9 degree of expansion. Reduction of turbulence provides the added benefit of reduced blood
10 clotting, since turbulent blood flow tends to create blood clots. As noted above, the increased
11 width of the stent members increases radio-opacity as well as increases contact with the
12 vessel wall as illustrated in Fig. 4G.

13 Figs. 5A-5D illustrate how the present invention may be utilized to cause a stent to
14 expand at its distal and proximal ends before it expands in its center region. A stent 210 is
15 shown positioned in an artery 9 adjacent plaque deposit 8. The central region 211 of stent
16 210 is positioned adjacent the plaque deposit 8. The central region 211 of stent 210 has no
17 relief cuts formed therein. The distal region 212 of stent 210 has a plurality of relief cuts
18 shown generally as 230 formed therein. Similarly, the proximal end 213 of stent 210 has a
19 plurality of relief cuts 231 formed therein. For the sake of illustration purposes, the relief cuts
20 230 and 231 in Figs. 5A-5D are simply shown as cross hatching or dashed lines. It is to be
21 understood that stent 210 may be any type of balloon expandable stent, including stent cell
22 configurations illustrated in Figs. 1-3 as well as a variety of other known stent configurations.
23 For example, The Stenter's Notebook published by Physicians' Press in 1998 and written by
24 Paul S. Phillips, M.D., Morton J. Kern, M.D. and Patrick W. Serruys, M.D. illustrates a variety
25 of commercial, balloon expandable stents at pages 181-206. Those pages are herein
26 incorporated by reference as though set forth in full herein. It is to be understood that the

1 relief cuts according to the present invention may be utilized in any of the balloon expandable
2 stent designs illustrated in The Stenter's Notebook. Some of those stent designs do not use
3 a plurality of closed cells, but rather use single wire shapes formed in a variety of ways. Each
4 of those designs has the common feature that a portion of the stent is designed to flex or bend
5 to allow the stent to expand. It is within the scope of the present invention to apply the relief
6 cuts of this invention to any of those prior art balloon expandable stent designs, preferably at
7 the points of those stent designs where the maximum flexing and bending are designed to
8 occur to allow the stent to expand. The invention may also be used in self-expanding stents,
9 as discussed below.

10 The stent 210 illustrated generically in Fig. 5A is intended to include any of the stent
11 configurations illustrated in The Stenter's Notebook, which are balloon expandable as well as
12 those configurations illustrated in Figs. 1-3 herein, and those shown and described in parent
13 application Serial No. 09/357,699, incorporated herein by reference as though set forth in full.
14 With the relief cuts formed at the distal and proximal ends 230 and 231, respectively, as the
15 balloon (not shown for clarity) expands, the distal and proximal ends 230 and 231 expand first
16 as illustrated in Fig. 5B. This feature can be very important since, as illustrated in Fig. 5B, the
17 distal portion 230 and proximal portion 231 of the stent will contact the vessel wall 9 before
18 the central region of the stent 211 contacts the plaque deposit 8, thereby tending to "trap" the
19 plaque deposit in its present position. As illustrated in Fig. 5C, the central region 211 of the
20 stent which does not have any relief cuts requires somewhat additional pressure to expand
21 and is shown in its expanded position where it contacts plaque deposit 8 and expands the
22 restricted part of the artery. Fig. 5D illustrates typical balloon pressures; the distal and
23 proximal ends 230,231 expand with 8 atm pressure and central section 211 expands at 10 atm
24 pressure. Other expansion pressures can be used; Fig. 5D is presented only as an example.

25 Figs. 6A-6C illustrate a stent configuration 250 having no relief cuts at its distal end 251
26 or at its proximal end 252. Stent 250 does have a plurality of relief cuts 255 according to the

1 present invention at its central region 254. As shown in Fig. 6B, the central region 254 having
2 the relief cuts expands first. This feature can be advantageous in preventing longitudinal
3 motion of the stent relative to the artery as it expands.

4 Fig. 7 illustrates yet another sinusoidal stent configuration 260 with relief cuts 265
5 formed only in its central region 261. That central region 261 will expand prior to the distal
6 and proximal regions 262 and 263, respectively.

7 Figs. 8A-8B illustrate how the present invention may be utilized to starve a cancerous
8 tumor 6 fed by an artery 9. A stent 270 is placed in the artery close to the cancerous tumor
9 6. Stent 270 has relief cuts formed only in its distal end 271. Stent 270 carries an
10 impermeable covering sheath 279 and, as its distal end 271 expands and contacts the walls
11 of artery 9, blood flow through artery 9 to tumor 6 is interrupted, causing the tumor to die.

12 Fig. 9 illustrates how the present invention may be used with a continuous, single
13 strand serpentine stent 280 known in the art. This type of stent is widely used in the art and
14 is illustrated separately since it does not use a closed cell design but, nevertheless, may
15 benefit significantly from the present invention. Relief cuts 281 are formed in serpentine stent
16 280 at the intended points of maximum flex or bending as the stent is expanded. Using the
17 relief cuts as illustrated in Fig. 9 will allow the stent to expand in response to less balloon
18 pressure. It is to be understood that the serpentine stent design could also be modified by
19 increasing the width of the serpentine stent member and decreasing the thickness, in similar
20 fashion as illustrated above in Figs. 4D, 4E and 4G relative to the prior art closed cell
21 diamond-shaped cell configuration.

22 Fig. 10 illustrates another variation of the invention wherein stent 290 has relief cuts
23 291 and 292 formed near apex 295. In the embodiment illustrated in Fig. 10, relief cuts 291
24 and 292 are aligned transversely across the width of stent member 296. This embodiment of
25 the invention is particularly useful for stents used in larger blood vessels and other body
26 lumens wherein adequate width is available to position the relief cuts transversely.

1 Figs. 11-14 illustrate various techniques by which the relief cuts of the present
2 invention may be used advantageously in curved or angulated arteries or other body lumens.
3 For example, Fig. 11A illustrates an artery 9 having a curved region 5. Artery 9 is assumed
4 to lie in a plane parallel with the drawing. Stent 310 is shown positioned in artery 9 in its
5 expanded position. Stent 310 has a distal section 311, a proximal section 312 and a central
6 section 313. The distant and proximal sections each carries a pattern of relief cuts illustrated
7 by dashed lines 315 and 316, respectively. Central section 313 of stent 310 does not have
8 relief cuts formed in it in the embodiment illustrated in Fig. 11A. The relief cuts 315 and 316
9 are not formed around the entire periphery of stent 310, as illustrated in sectional view 11B.
10 As shown in sectional view 11B, relief cuts 315 are formed in the upper part and lowermost
11 part of stent 310; however, no relief cuts are formed near the horizontal axis A illustrated in
12 Fig. 11B. The effect of placing relief cuts as illustrated in Fig. 11B is to allow stent 310 to
13 bend easily relative to vertical axis B-B in order to accommodate the curved section 5 of artery
14 9 to facilitate deployment of stent 310. The pattern of relief cuts as illustrated in Figs. 11A and
15 11B tends to maximize the strength of stent 310 in its central region 313 to resist the
16 crumpling of the curved region 5 of artery 9.

17 Figs. 12A and 12B illustrate a variation to the relief cut pattern shown in Fig. 11. Stent
18 350 illustrated in Fig. 12 has relief cuts 355 formed along its entire length including central
19 region 353 as well as distal and proximal ends 351 and 352. Again, the relief cuts 355 are
20 only formed away from the horizontal axis A-A illustrated in Fig. 12B. Placement of the relief
21 cuts in this fashion allows the stent 350 maximum flexibility to bend about vertical axis B-B
22 illustrated in Fig. 12B to facilitate its placement and deployment in the curved artery 9.

23 Figs. 13A and 13B illustrate yet another manner in which relief cuts may be utilized to
24 facilitate deployment of stent 410 in curved artery 9 having a curved section 5. In this
25 embodiment, the pattern of relief cuts 415 is only formed in the central region 413 of stent
26 410. The proximal end and distal end 411, 412 have no relief cuts formed therein. Central

1 section 413 has relief cuts formed completely and uniformly around its periphery as illustrated
2 in sectional view 13B. Placement of relief cuts around the entire periphery of the central
3 region 413 allows maximum flexibility of stent 410 in the region where stent 410 must bend
4 to conform to the curved region 5 of artery 9.

5 Figs. 14A and 14B illustrate stent 450 having a pattern of relief cuts 455 placed only
6 at the central region 453 of stent 450 and only in that portion of the stent periphery which
7 contacts the outside radius of the arterial wall at the curved section 5. As illustrated in Fig.
8 14B, relief cuts 455 are placed radially outwardly of the vertical axis B-B of Fig. 14B and no
9 relief cuts are formed on the inside radius, that is, radially inwardly of the central vertical axis
10 B-B of stent 450. The purpose of placing relief cuts in this fashion is to allow the central
11 portion 453 of stent 450 to flex to conform to the curved portion 5 of artery 9 while
12 simultaneously allowing the stent to remain as rigid as possible adjacent the more sharply
13 curved arterial wall region 4 which occurs at the radial inwardly side of the curved section of
14 artery 9. The stent is therefore strongest along the inside radius 4 of curved artery 9, which
15 is the part of the artery most likely to crimp.

16 Figs. 15A and 15B are schematic illustrations showing how the present invention can
17 be used in conjunction with bifurcated stents. A bifurcated artery 9 splits into two branches
18 2 and 3. A first prior art stent 470 is placed in artery 9 and has an extension 471 that extends
19 partially into branch 2. A second stent 480 is provided having a series of relief cuts 485
20 formed in its distal end 481. The distal end 481 of stent 480 is positioned inside stent 470
21 prior to being expanded. As shown in Fig. 15B, as stent 480 is expanded, its distal end 481
22 forms a "flare" 482 which effectively seats against stent 470 and which prevents stents 470
23 and 480 from separating after being deployed.

24 Figs. 16A and 16B are schematic illustrations showing how the present invention can
25 be utilized in arteries or other lumens having somewhat irregular shapes. Artery 109 is shown
26 having a first section 109a of rather large diameter and a second section 109b having a

1 somewhat reduced diameter. Plaque deposit 108 is illustrated in the generally tapered region
2 of artery 109. A stent 510, which can be any prior art stent or any stent shown and described
3 in the parent application referred to above. Stent 510 has a distal end 511 and a proximal end
4 512. A rather large number of relief cuts 515 are formed in proximal end 512 of stent 510.
5 A somewhat smaller number of relief cuts is formed in the distal end 511 of the stent 510. The
6 purpose of placing these patterns of relief cuts on stent 510 is to cause the stent 510 in its
7 expanded position to conform as closely as possible to the walls of the artery 109 and the
8 plaque deposit 108. As shown in Fig. 16B, the proximal end 512 expands further because of
9 the presence of a greater number of relief cuts 515. The distal end 511 expands a somewhat
10 reduced amount because of the absence of relief cuts. The small pattern of relief cuts 516
11 formed near the distal end 511 causes a somewhat greater expansion of stent 510 in that
12 region to conform to the shape of the arterial wall and plaque deposit 108. Figs. 16A and 16B
13 illustrate how patterns of relief cuts can be utilized to make a stent expand in a controlled non-
14 uniform fashion to conform to a somewhat irregularly shaped arterial wall. The stent in its
15 expanded form effectively supports the irregularly shaped vessel wall and plaque deposits and
16 simultaneously seals off any leaks that would otherwise occur at the proximal and distal ends
17 of the stent.

18 Figs. 17A and 17B are schematic illustrations showing how the present invention may
19 be utilized in an artery or other lumen having a branch artery at or near the location where the
20 stent is to be deployed. Artery 209 has a first region 210 of relatively large diameter and a
21 second downstream region 211 having a considerably reduced diameter. A branch artery 212
22 connects to artery 209 near a plaque deposit 208. Stent 550 is provided having a distal end
23 551 and a proximal end 552. Since the proximal end 552 must expand a greater distance
24 than the distal end 551, a relatively large number of relief cuts 555 is placed near proximal
25 end 552. The number of relief cuts is gradually reduced and, at the center of stent 550, a
26 relatively sparse pattern 556 of relief cuts is applied where the stent should be expanded the

1 least. Towards the distal end of stent 551 a secondary pattern 557 of relief cuts is applied so
2 that the stent may expand to a somewhat greater degree adjacent the distal end 207 of plaque
3 deposit 208. Stent 550 is shown in its expanded form in Fig. 17B and it can be seen that the
4 patterning of relief cuts allows the stent to expand in a controlled non-uniform fashion to
5 conform to the walls of the artery 209 and to achieve the desired blood flow through artery
6 209.

7 Figs. 18A and 18B show an alternate stent design 610 which may be utilized in the
8 irregular shaped artery 209 illustrated in Figs. 17A and 17B with plaque deposit 208 and
9 branch artery 212. Stent 610 has a proximal end 611 and a distal end 612. The proximal end
10 of stent 610 extends beyond the location where branch artery 212 connects with artery 209.
11 Stent 610 has an opening 614 formed in its surface adjacent where stent 610 will expand
12 against the base of branch artery 212. The opening 614 in stent 610 allows blood to flow
13 freely from artery 209 into branch artery 212. Stent 610 has a greater number of relief cuts
14 615 formed at its proximal end 611 as compared to the relief cuts 616 formed at its distal end.
15 A tapering pattern of relief cuts 617 is formed in the center of stent 610 to allow the stent to
16 conform to the required taper. As shown in Fig. 18B, the relief cut patterns are designed to
17 allow the stent to expand in a controlled, non-uniform manner to conform to the wall of the
18 artery (or other lumen) and to prevent end leaks.

19 Fig. 19A illustrates a prior art stent design 650 shown in U.S. patent No. 6,159,237,
20 wherein the stent includes transverse cells 651 and 652. As stent 650 expands, cells 651 and
21 652 expand along the longitudinal axis A-A of the stent 650.

22 Fig. 19B shows the relief cuts of the present invention as applied to the stent design
23 650 of Fig. 19A. Relief cuts 655 allow stent 650 to expand radially in a first direction to
24 increase its circumference. Relief cuts 656 in transverse cells 651 and 652 allow cells 651
25 and 652 to expand more easily in a second direction parallel to longitudinal axis A-A. Fig. 19B
26 illustrates how the present invention can be used to facilitate stent cell expansion in two

1 directions (longitudinally and circumferentially) simultaneously. Alternately, relief cuts 656 in
2 the transverse cells may be utilized without using relief cuts 655; this variation would allow the
3 transverse cells to expand more easily than the circumferentially expanding cells. Also, relief
4 cuts 655 may be used without using relief cuts 656.

5 Although the above description of the invention has concentrated on balloon
6 expandable stents, the invention is also useful with self-expanding stents. In the case of self-
7 expanding stents, the use of relief cuts allows the use of flatter and thinner walled stents,
8 increasing the radio-opacity and vessel wall coverage of the stent. Furthermore, using
9 patterns of relief cuts in self-expanding stents, those stents may be caused to expand in a
10 controlled, non-uniform fashion which can be advantageous in many situations. Each of the
11 figures illustrated herein, including the various stent cell configurations and the various
12 patterns of relief cuts illustrated in the drawings, may all be applied to self-expanding stents.

13 The present invention is usable with stents made of any material such as nitinol,
14 stainless steel, plastic and composite materials.

15 The foregoing description of the invention has been presented for purposes of
16 illustration and description and is not intended to be exhaustive or to limit the invention to the
17 precise form disclosed. Many modifications and variations are possible in light of the above
18 teaching. The embodiments were chosen and described to best explain the principles of the
19 invention and its practical application to thereby enable others skilled in the art to best use
20 the invention in various embodiments and with various modifications suited to the particular
21 use contemplated. The scope of the invention is defined by the following claims.